

Material Transfer Agreements: A University Perspective

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One of your colleagues at BigAg, Inc. (or at BigAg University) says that she'd be happy to send you her transposon insertion lines that saturate the right arm of chromosome 9; you'll just need to have a material transfer agreement (MTA) signed by your institution. Six months later, the terms of the agreement are still under negotiation, you've missed the field season, your grant has expired and there is now a better resource that's been developed at LittleAg University—and if you start negotiating an MTA now... Welcome to the increasingly complicated world of sharing research materials—those biological materials or reagents that are often essential, or at least helpful, to accelerate your own research.

The tremendous advances in molecular genetics since the early 1980s brought an increased sophistication in research approaches that rely heavily on access to biological or bioinformatic resources that have been created by other researchers. This trend has been advanced further by the investment of federal agencies (notably the National Science Foundation [NSF] and the National Institutes of Health [National Institutes of Health]) and private companies in the development of genomic resources that are intended primarily as vehicles for further discovery of gene function and/or gene regulation. These types of biological and bioinformatic resources (i.e. insertional mutant populations, genome sequence databases, or novel vectors) are the most problematic with regard to sharing because they are the research tools that can lead to potentially valuable discoveries, and this invariably leads to the question of who will own or control those downstream discoveries. The NIH views the sharing of research tools to be so important to future research progress that it issued strong guidelines on the appropriate terms for transfer of research materials that contribute to, or result from, NIH-funded research (Marshall, 1999; <http://ott.od.nih.gov/newpages/RTguide.htm>). Similarly, the NSF, particularly in programs such as the Plant Genome Research Program that focus on the generation of research resources and tools, has specific guidelines for data and materials release and requires investigators to describe the timing, constraints, and means of release of materials developed (Silverthorne, 2003).

Scientists have traditionally shared research materials freely, and indeed an important criterion for scientific publication has been the unfettered ability of other researchers to experimentally reproduce and thereby test published results. That ability to replicate results will often rely on access to the underlying biological materials or information, but that access is not assured today. So what has changed? Probably the most significant factor has been the narrowing of the gap between fundamental research and commercial developments, particularly in the biomedical arena, but it is also evident in agricultural biology (Rai and Eisenberg, 2001). Materials that at one time would have been useful almost exclusively for fundamental research purposes are increasingly seen as having direct commercial value, and this has generated a new breed of company that focuses on leveraging novel research tools to discover new commercially valuable traits, genes, or compounds. Naturally, these companies are reluctant to share their "crown jewels" without making sure that their business interests are protected. Also of significance has been the changing role of universities, which are today actively using the patent system as a means of transferring its research results into the private sector and often conduct research that is sponsored by private companies. The increased use of the patent system is largely a consequence of the passage of the Bayh-Dole Act in 1980, which allowed universities to own and manage inventions made under federally sponsored research, provided that they filed patent applications and made diligent efforts to further develop and commercialize the invention (see http://www.cogr.edu/docs/bayh_dole.pdf). For these reasons, companies that traditionally had little concern over a university's use of its property may now be appropriately concerned over how its proprietary materials may lead to valuable inventions or even to fuel a competitor's business interests. Universities and non-profit research institutions have followed suit and have also become much more aware and protective of research materials. The result has been a slow but steady evaporation of unrestricted transfers of research materials between scientists in general but particularly between industry scientists and those in universities.

With growing regularity, the sharing of research materials takes place under MTAs, which are legal agreements (bailments) that govern the transfer of a tangible property between parties. For example, the

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www.plantphysiol.org/cgi/doi/10.1104/pp.103.026658.

nine campuses of the University of California system executed almost 2,000 MTAs in 2002, up 30% from the previous year. At the same time that the numbers of MTAs are increasing, so is their complexity, with restrictions and obligations potentially reaching far beyond the material itself, to data or inventions made using the material and/or to derivative materials. Because MTAs are contractual agreements between two parties, they typically do not have the geographic or temporal limitations of patented technologies and can consequently be much farther reaching than the scope of patent rights. It is interesting to note that an evaluation of the property rights associated with "GoldenRice" indicated that 44 patented products or processes and at least 15 materials, many of which were governed by MTAs, were potentially used in its development (Kryder et al., 2000). In navigating the intellectual and technical property landscape surrounding "GoldenRice," Potrykus (2001) reported that the unfair use of one MTA had been particularly problematic.

Just as universities are experiencing an increase in the use of MTAs to receive and disseminate materials, so are companies. One large pharmaceutical company indicated that it had six administrators dealing with more than 1,000 MTAs in 2000, and many of these agreements required lengthy negotiation. It has been suggested that some companies have questioned whether it is worth their while to exchange research tools with university scientists at all (Eisenberg, 2001). In our own experience, agreements for transfer of research materials from industry to the university often have a low priority for attention within company legal departments, particularly because such transfers are often only incidental to, or may actually compromise, their main commercial interests. From the university perspective, we estimate that 10% to 25% of MTAs received from industry for incoming materials to the University of California are never executed because the terms compromise fundamental academic principles or create legal obligations that the university cannot fulfill. Thus we are in a situation where the exchange of research materials is of increasing and indeed critical importance, but both universities and private companies are having difficulty finding easy ways to share these resources. As Eisenberg (2001) summarized "Although there are many points on which they disagree, most people from each of these quarters seem to agree that the problem is growing rather than diminishing."

MATERIAL TRANSFER BETWEEN UNIVERSITIES

Sharing of materials between university scientists is the least problematic, primarily because the cultures and motivations of each institution involved in the exchange are similar. Because the vast majority of university research is funded by relatively few federal agencies, the policies associated with their grant

support also has a strong influence on how results of research are disseminated and shared. Most universities readily transfer material for academic research purposes under terms that typically have no restrictions other than a restriction not to transfer the material to third parties without approval or notification. These transfers are often accomplished using the NIH-facilitated Uniform Biological MTA (<http://ott.od.nih.gov/newpages/UBMTA.pdf>) or an equivalently benign agreement. When a problem does occur in a transfer between academic institutions, it is usually because the material has been exclusively licensed and the terms of that agreement impose some constraints on the providing institution. However, this is usually avoidable. For example, even in the case of patented materials that are licensed for commercial development, the University of California specifies in its license agreements that it reserves the right to use the materials for internal research purposes and to transfer the materials for research at other academic institutions.

MATERIAL TRANSFER FROM PRIVATE COMPANIES TO UNIVERSITIES

Material transfers between private and public sector institutions are typically much more complex than transfers between two universities and are much more prone to failure, particularly when the transfer is from a company to a university researcher (Pool, 2000). What are some of the features of these MTAs that universities find so hard to accept? Contrary to popular belief, the primary issues for most universities do not concern the ability to profit from licensing future inventions but center on (a) a few fundamental academic principles, (b) the need to avoid incurring financial obligations, or (c) the need to avoid creating conflicting legal obligations with third parties. These issues primarily reflect the low tolerance most universities have for financial or legal risk and their concern with protecting the fundamental mission of the institution.

Dissemination of Research Results

The single most obvious and fundamental principle for the university and university researchers is to preserve the unrestricted ability to disseminate their research results—e.g. to publish. The freedom to publish can be restricted by MTAs when the provider requires editorial rights in a publication or the right to approve, and by inference to disapprove, a publication. Publication restrictions can show up in MTAs in indirect ways as well. For example, the material itself may be specified as confidential, making a meaningful publication impossible. Of particular concern are the serious consequences that a publication restriction can have on students, whose future depends so heavily on publication. Clearly, this is

one principle the university cannot compromise and is so widely recognized that one would think that it would not even be on the table for discussion. However, it often is.

Typically, the material provider's underlying concern is not to restrict academic publication but to protect its confidential information that may be related to the material and to preserve patentability of inventions. Both are legitimate concerns and can be met by agreeing to remove a company's confidential information from publications and to delay publication for a limited time (usually 60–90 d) to permit filing of patent applications. Universities readily agree to these types of provisions but further restrictions on publication rights are typically nonnegotiable.

Rights in Research Results

University researchers also need to preserve the ability to use their own research results in future research. Again, this may seem obvious, but if a provider of material insists that it own the results of research conducted with its material (sometimes including data, inventions, and reports), researchers and universities can lose all access to these products of their own research, making it difficult, if not impossible, to perform any follow-on research. An example of how this appears in an MTA is when a provider asserts ownership of new substances created by the university researcher while using its proprietary material, sometimes reaching to substances or compositions that do not contain the original material in any form (often referred to as “reach through” rights). This type of provision could have an impact on publication as well, because many journals require that materials discussed in a paper be made available for replication of the research, yet in this case, such availability would be controlled by the material provider, not the researcher. In many cases, there is a legitimate reason why the provider of a material would insist on retaining ownership of any modifications of the original material. For example, if a vector that took years to create could now be easily modified to incorporate new functions, the provider would be understandably reluctant to relinquish rights to improvements that can now be relatively easily incorporated. In these cases, it may not be appropriate or possible to share this material. However, in many cases, this kind of provision is the result of a provider using too broad of an approach to ensure no possible loss of its own rights. Negotiations can often identify a balanced solution where the provider is assured that it maintains ownership of its proprietary material, including in improvements where the original material can still be identified as a component.

Conflicting Legal Obligations

Perhaps the most difficult area in university MTAs is the potential for entering into agreements that create conflicting legal obligations. This situation routinely arises because, although the material is coming from one source, the funding for the research is usually provided by a completely different source, typically from government agencies but also potentially from other private companies. To the extent that the MTA and potentially multiple funding sources carry intellectual property obligations, it is easy to see how conflicting obligations can arise. Although such obligations are typical of private research support, federal agency funding also carries legal intellectual property obligations to the government. The most prominent of these obligations include the requirement under the Bayh-Dole Act to provide a nonexclusive license to the government to practice or have practiced the invention on behalf of the United States. Clearly, the university cannot enter into an MTA that creates a new obligation that is in conflict with obligations of law or its contractual obligations to others. For example, if access to a particular research tool or material requires that the provider is offered an exclusive license to inventions, then this restricts the project from receiving any other material or research funding that carries a similar obligation—exclusive access to inventions from the same project can only be given once! The university or researchers need to be very careful in determining how important specific inputs to the project are and may need to prioritize what intellectual property rights can be apportioned to research sponsors and/or material providers. It is clear from the complexity of inputs to research projects and the increasing complexities of ownership of research tools and materials, that access to the full set of tools for certain projects may simply be impossible. This situation is analogous to what has been described as the “tragedy of the anticommons” where the fragmentation of intellectual property ownership becomes so complex that no single entity can acquire all the rights that it needs to develop products (Heller and Eisenberg, 1998). In a similar sense, the fragmented ownership of research materials or information can impact the practical ability to conduct fundamental research or at least to do so using the most efficient research tools.

Public Benefit of University Research

Universities, particularly public universities or those whose research is supported largely by government funds, have an obligation to see that their innovations are made available to the public in a diligent and timely manner. This obligation is based, in part, in the Bayh-Dole Act, which has a stated objective “to promote . . . public availability of inventions” as well as in the philosophical mission of most uni-

versities and particularly of land-grant universities. One means of accomplishing this is through licensing of inventions to private companies who can invest the additional research and development effort required to produce real products. The public benefit obligation can be compromised by MTAs that require the grant of a nonexclusive, royalty-free license to inventions. If the company were not interested in commercializing the invention itself, the existence of its nonexclusive, royalty-free license could prevent other companies from entering into a license because they would lack the exclusivity needed to justify investing in the development of the technology, effectively "shelving" the technology. A solution that is often acceptable is to link such a license very narrowly to inventions that are dependent on the company's material. These inventions represent the company's legitimate business interest and are inventions that typically only the company providing the material would be in a position to commercialize. Although broader language seeking a license to inventions less closely linked to the material will not necessarily prevent a university from signing an MTA, it should certainly provoke a careful evaluation of the situation.

Fair Consideration

Most universities also seek to receive some financial return in exchange for the commercial use of their research results. Public institutions, in particular, are concerned that the public funds that are used to support the institution are not used to indirectly support private companies. There is also a technical issue surrounding how the Internal Revenue Service views the private use of buildings that are financed by tax-free bonds, and in many cases, license agreements that provide free access of intellectual property to private companies have the potential to jeopardize the tax-exempt status of the bonds. Because many, if not most, university buildings are financed at least in part by tax-free bonds, this is becoming a serious issue for universities and an obstacle for the establishment of strong university-industry relationships.

These considerations color the expectations of universities particularly if the provider of a material seeks a free license to resulting inventions. Here, the university administration and researchers may diverge in their own interests, with the researchers needing primarily to gain access to the material to advance their research and the university seeking to preserve its fundamental principles and avoid costly legal battles. Needless to say, these situations can become very complex, with the interests of the re-

searcher, the company and the university not necessarily in alignment. In our experience, a common underlying interest of all parties is to enable and accelerate research progress, and in most cases, solutions can be developed that satisfy the essential needs of all parties. Unfortunately, developing these solutions can take a long time, and as indicated above, for many private companies, negotiating MTAs for university researchers is a low priority in relation to the many intellectual property-related transactions that are more critical to their primary business interests.

CONCLUSIONS

Overall, the transfer of materials between researchers has been getting more difficult, and it appears that the days of open exchange of materials, particularly from researchers in industry to academic researchers in the life sciences, are over. Although some domains of free exchange continue to thrive and funding agencies, such as the NSF and the NIH, are actively promoting open exchange of materials, these are becoming exceptions rather than the rule. Universities and private companies each have very legitimate interests that they are trying to support when engaging in material transfers and when these interests collide it can be very difficult to find common ground. However, the mutual interest of both research-based private companies and of universities is to support research advances and when both parties keep this overarching objective in mind, most material transfers are possible.

Received May 8, 2003; returned for revision June 9, 2003; accepted June 9, 2003.

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